Frequently Asked Questions Version 11.06.2021

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FAQ FOODSUP

We highly advise you to read both the user manual and the FAQ carefully before contacting us.

Please refer to the ad hoc pages (only in French or Dutch) regarding labeling (<u>https://www.health.belgium.be/fr/alimentation/informations-aux-</u> <u>consommateurs/etiquetage/regles-detiquetage</u>), claims and publicity (<u>https://www.health.belgium.be/fr/alimentation/informations-aux-</u> <u>consommateurs/allegations-et-publicite/quest-ce-quune-allegation</u>) of foodstuffs. FAQ additives (only in French or Dutch): https://www.health.belgium.be/fr/faq-additifs

If you want to contact us, please specify the product-related information (company's name and number, file number, product name).

1. How do I register to FoodSup?

The registration occurs in two stages. You first need to register the e-mail address of the responsible in accordance with the instructions as provided for in Section 4.1 of the User Manual. The second stage consists of sending us the signed Annex 1 (local admin) by e-mail.

2. I work as consultant and I have to notify products for my clients.

Consultants are asked to register following the same procedure as for company's responsible persons, stating that it is a consultancy firm. Companies which give a delegation to a consultant have to send the signed Annex 3, specifying the name of the consultancy company. Annexes 3 signed by the consultant will not be accepted.

If the company wishes to give a delegation for one or several products already notified, the table at the bottom of the annex must be filled in.

Be careful: In case of transfer division, the delegations given to the division that are been taken are automatically cancelled.

Please note that a list of consultants is available in FoodSup. The inclusion on the list of consultants is not a recognition of expertise or experience and does not engage the responsibility of the FPS of Health.

3. When I log in, I have a message indication I am not linked to an organisation.

Please refer to point 1 of those FAQ: You have registered your e-mail address but you didn't send annex 1 yet and/or the access has not been granted by the FPS.

4. I cannot have access to FoodSup as I did not receive my password.

We do not send any password. When you register (see User Manual, Section 4.1), you have to choose a password. If you lost or forgot it, you can ask for a new one (see Section 4.3.1).

5. My account has been blocked...

When the user encodes three times the wrong password, the account will be blocked. After half an hour the account will be unblocked and a new password can be asked through the lost password module (see Section 4.3.1).

6. I have created a shortcut and now I cannot log in.

The module to log in uses a few redirects, check if the right url (www.health.belgium.be/foodsup) was saved (click right -> properties).

7. I am a local admin and I wish to give access to my colleagues. Do I have to send Annex 1 for each of them?

There can be only one Annex 1 per company (= 1 local admin). The local admin can give access to other users by following the procedure outlined in Section 8 of the User Manual. Please follow the whole procedure. You can request a modification of local admin by using Annex 2. You should never change/delete your local administrator yourself, otherwise the account will be blocked.

If a user should no longer have access to the system, it is possible to withdraw his or her access (apart from the local administrator). His/her name can always be included in the list of contact persons because his/her name is linked to files. If you no longer want the name to appear in the drop-down menu of contact persons in files, simply inactivate the contact details.

8. The composition of my product is confidential and my manufacturer does not want to give me the information required for the notification. What can I do?

The information we receive is confidentially. The qualitative and quantitative composition must be mentioned in the notification file. Sometimes manufacturers do not want to provide such information straight to their customers; in such cases, they can send the information to us instead of to their customers. In that respect, the responsible notifies the product and clearly stipulates that the information will be forwarded directly by the manufacturer. The field "Ingredients and composition will be provided by a third party for reasons of confidentiality" has to be flagged. We will encode the information in FoodSup so as to make it available to the competent bodies but without making it visible for the responsible. The information must be provided to our Service no later than 10 days after the submission of the file.

Please note that if you flag the field mentioned above, the responsible will be <u>forever</u> denied access to ingredient quantities.

9. I do not find an ingredient among those listed in FoodSup.

First of all, you have to check if it does not already exist in the list by using our search engine and by typing in pieces of words to search for. Please make sure you spell the word correctly and use the right accents. Searching by E number is recommended as far as additives are concerned.

If the ingredient cannot be found, please contact our Service at the following address: <u>apf.sup@health.fgov.be</u> in order to study the addition of the new ingredient in the database.

10.I want to introduce non active ingredients in my food supplement.

The regulation on food supplements is not based on the activity of ingredients but only on their presence in the product. Cannot be considered as additive an ingredient covered by the European

regulation on additives (Regulation 1333/2008 (in particular the use of E-numbers)), else ingredients must follow the specific regulations on nutrients, plants¹ or other substances.

11. What is the maximum size of the annexes?

Each document must be less than 10 Mb in size.

12.Can I put information in the file annexes?

It is possible to put information in the annexes of the file. However, information like the list of ingredients and or the different tables of the file must mandatory be encoded in the different tables of FoodSup (or in the paper form for mail or postal submissions). If the information is in the annexes but not in the file itself, they will be considered as missing.

13.Can I put symbols like * or % for searches?

No.

14.If I find an ingredient in the list, does it mean that the use of that ingredient is permitted?

The list of ingredients in FoodSup is neither a positive nor a negative list. It contains all ingredients listed in the present or former food legislation, as well as ingredients reported by operators. Please click "view" to the right of the ingredient as we may have put potentially useful information.

15.How must be declared ingredients that can be nutrients or additives (E-number)?

It all depends on the function of the ingredient in the product. You always must indicate the right function on the label and in the FoodSup file. An ingredient cannot be the same time nutrient and additive.

For example, L-ascorbic acid used as a chemical form of a nutrient (Vitamin C) **or** ascorbic acid used as additive E300.

You must choose in Foodsup nutrients under the type "chemical form of nutrient" in the search engine and the type "additive" for additives. For additives, you can also make a search by E-number.

16.Why are there no warnings for ingredients/nutrients/active substances/... that are overdosed but only technical validations when a notification is submitted?

This is a very deliberate decision made during the analysis before FOODSUP was developed. The main elements that have led to this decision are:

- the way limits are expressed in the legislation: some limits are expressed per daily portion, others by kg, l, ... of the product, some limits are applicable on the product as such, other on the product after preparation following the instructions of the responsible, ...

- the way data are encoded: in order to implement a check on the composition of a product, FOODSUP would need much more structured and mandatory fields than it is the case now.

17.Is the full list of ingredients mandatory in the notification file of fortified foodstuffs?

For fortified foods, the file must contain the chemical forms of the nutrients and their quantities as a minimum. Those quantities must be expressed per portion as recommended for daily consumption

¹ See point 24.

on the labelling (or per quantity of food equals to its mean daily consumption as foreseen in annex 2 of the RD of May, 30th 2021).

It is not mandatory to mention the other ingredients and their quantities in the notification file. If the fortified food contains plants from list 1 of the RD of August, 29th 1997 (RD on plants), those information must always be mentioned in the notification file.

Be careful: It is always possible that our Service asks more information and makes comments about ingredients other than added nutrients.

For food supplements, the qualitative and quantitative list of ingredients is mandatory.

18. What must contain the nutrition declaration of fortified foods and how must it be expressed?

The nutrition declaration must contain as a minimum the energy value, the total fat, the saturates, the carbohydrates, the sugars, the proteins and the salt intakes, as well as the vitamins and minerals added in the product. It must be expressed by 100 g or 100 ml, the portion declaration is optional. Vitamins and minerals intakes must also be expressed in % of reference intake. The nutrition declaration must be presented as a table (or the declaration shall appear in linear format where space does not permit), but some elements must be repeated in the front of pack.

The FPS Health, Food chain safety and Environment has designed a <u>flowchart</u> (available in FR or NL) to facilitate the implementation of the nutrition labelling rules. ATTENTION: For a right application of the legislation, please refer always to the Regulation itself

19.Is the nutrition table as foreseen in Regulation 1169/2011 mandatory for food supplements?

According to article 8 of Directive 2002/46/EC, only nutrients quantities or substances with nutritional or physiological effect must be indicated for food supplements. They must not be expressed by 100 g or 100 ml, but by recommended daily dose in the labelling.

On a voluntary basis, the nutrition table may be mentioned, provided that the requirements of Regulation 1169/2011 are met (except for the recommended daily dose). In this case it is therefore necessary to mention at least the energy value as well as the contents of fat, saturated fatty acids, carbohydrates, sugars, proteins and salt. ATTENTION: this interpretation is not shared by all Member States and is therefore likely to be reviewed in the future depending on developments at European level.

20. When and how do I pay the notification fee?

If you have submitted your file through FoodSup, you will receive the invoice by email indicating the deadline for payment. The invoice can also be found in the annexes to the file, under "invoice". A series of 11 or 12 numbers starting with 117 will be specified on the invoice and must be only and mandatorily communicated in the payment transfer request. Please never mention any other information or symbols (no "+++" nor "/") here. Only one payment per product is authorized.

We advise you to pay the fee as quickly as possible instead of waiting until the payment deadline, otherwise the processing of your file might be delayed.

Regarding files submitted by email or by post, the file must be sent without prior payment. Our Service sends the applicant the invoice corresponding to the file. The payment must be made according to the indications mentioned on the invoice. The proof of payment must be sent before the payment deadline and complete the file in accordance with the requirements of the RDs on Nutrients, Plants and Other Substances. The date of receipt of the payment represents the official date of submission of the complete file.

The fee is 180€ for files submitted through FoodSup and 200€ for files submitted by email or by post. Bank fees are totally at charge of the applicant.

21. Wat is the VAT-number of the FPS?

The VAT-number of the FPS is : BE0367303762. Please note that the fees are not subject to VAT.

22.I have mentioned the wrong name (company or consultant) on the invoice.

Can you put it right?

No, we cannot.

23. The product name, the name of the responsible or the address is incorrect. Can you correct the invoice and/or the file that have been generated?

No, we cannot. The system does not allow us to make such corrections. You will have to modify your file to correct the mistake by yourself. However, invoices can never be corrected.

24.I cannot submit my file as I am being told that some ingredients are inactive.

Such warning can be found mainly in files submitted to us before starting to use FoodSup. As a result of legislative changes, inactive ingredients are no longer accepted. Most of them are ingredients for which the indication "chemical form undetermined" is stated, for plant names ending with "*spp*" or plants preparations not indicated under their Latin name like juices or oils for example. If you receive such message, you have to replace the inactive ingredients by ingredients provided for in the law. If you cannot find the inactive ingredients of your product, please contact us and mention the file references.

25.What should I do with pack products?

"Pack" means one product (packaging) that consists of more than one product, for example capsules for the morning and capsules for the evening. As every list of ingredients has to be encoded separately, those products have to be encoded as two separate products and a difference needs to be made in the name of the product. For example: XXX [pack 1/2: day/yellow capsule] and XXX [pack 2/2: night/white tablet]. Both products will therefore have a different number (which was not the case before). If the products are never going to be sold separately, only one invoice should be paid.

If the product has been notified before FoodSup is in use, you have to split the pack in as many files as there are components. Don't forget to change the name of the file.

26.The composition of my product is going to be adapted. Should this adaptation be notified ? How?

All the adaptations related to the composition must be notified, so that the notification file reflects the product on the market. Depending on the type of ingredient, these adaptations should be notified as a modification of an existing notification, or as a new notification (product considered as a new product). A new notification has to be introduced if there is a qualitative or quantitative change of one or several ingredients which are not authorized additives, aromas, nor the chemical form of a nutrient. If the daily portion is modified, a new notification must also be submitted.

For changes related to an authorized additive, an aroma or the chemical form of a nutrient (without change in the nutrient equivalent), a modification of file can be introduced.

Please note that a modification can never be the first version of a file.

27.My product has several tastes. May I send only one file?

If the products only differ in their natural or artificial flavouring, you are allowed to send only one file, with indication of all flavours in the title of the file and all labelling of the products available. If the difference consists of using a plant (chocolate, banana, etc.) or means adding, removing or modifying the quantity of an ingredient, the products have to be notified in separate files.

28.I have a product sold in different packaging sizes, can I send only one file?

If the products differ only in the number of capsules per package, for example, only one file can be sent with the indication of all package sizes in the 'product' table of the folder and all available product labels. If there are several galenic forms, the products must be notified under different dossiers.

29.I cannot find the reply you sent to me.

For all files processed in FoodSup (since October 2012), a copy of the reply is available in the annexes to the file.

30.My notification file doesn't reflect anymore the product put on the market (other commercial name, composition, labelling or product no longer marketed). What should I do?

The notification file must correspond with the product on the market. It is up to the operator to check if the files are in order and to update them when applicable.

For composition changes, see answer to question 26.

If the commercial name of a product changes, the product with the new commercial name will be considered as a new product and a new notification should be introduced. Notifications with several commercial names are not accepted anymore.

Changes in the labelling (not related to composition or commercial name) should be notified by introducing a modification of file.

If a product is no longer marketed, you can let it know by clicking on the icon "withdrawn from market" (see point 6.6 of the Foodsup user manual). A modification of file should not be done in this case.

31.I wish to submit my file, but I get an error message showing a triangle with an exclamation mark inside.

As explained in Section 6.3.1 of the Manual, such information applies to "gentile warnings". You then can submit your file even if some information is missing. Please note that the missing information can be mentioned in our reply.

32.I cannot submit my notification because of error messages.

See Section 6.3.1 of the User Manual.

33.I am a consultant and I wish to have a copy of the reply.

Consultants receive a copy of the reply by email if they have submitted the file through the on-line portal. In any other case, they have to contact the company that hires them.

34.I still have not received an answer concerning my file in draft.

If the state of your file is "in draft", it means that it has not been submitted to our Department. You have to click "Submit". A file that has been submitted and for which there has been no answer yet can be found under "products waiting for decision".

35.I want to be sure that my file is complete or will be approved. May I send it in advance by email for agreement?

No. We do not preprocess files. Please consider sending your file early enough so that potential problems can be solved before the product is placed on the market.

36. My file is a priority. Can you process it before other files?

No. Files are processed according to the date of receipt.

37. Which products are visible in the WWW-module?

The WWW-module only shows products for which an administrative number has been granted. The administrative number is neither a recognition of the conformity of the product nor a recognition of its status and cannot be considered as a marketing authorization. However, products for which it has been indicated that they are withdrawn from the market are not visible. Administrative numbers are used as a reference for companies to contact the authorities.

The WWW-module only shows the name of the product, the name of the responsible and the notification number. The WWW-module is update in real-time.

In the WWW-module, you will find three types of products: those for which there is no logo after the number which represent dossiers for which no major infringement has been detected at the time of their submission, products with the logo of a magnifying glass which are dossiers for which an opinion must be requested from a commission (for an derogation for example) and finally, dossiers with the logo of the danger symbol for which at least one major infringement of the legislation has been detected.

38.I made a mistake in a submitted file, can I delete it?

A notification that has been submitted cannot be removed neither by the responsible nor by our Department. Be very attentive before sending files. If you still find an error after submitting, please submit a modification.

39.My file has been given a number with a code (d) and appears with an exclamation mark on the public list of notified products, what does this mean?

If a file has been given a number with a code (d), it means that at least one serious infringement of food law has been detected on the basis of the administrative file. The product cannot be made available to the consumer until it has been brought into conformity. Compliance must be notified to the FPS by means of an amendment to the file.

40.My file has been given a number with a code (c) and appears with a magnifying glass on the public list of notified products, what does this mean?

If a file has been given a number with a code (c), this means that the file has to be assessed, usually by a specific commission. Making the product available to the consumer should await the conclusions of the evaluation, the product having to be adapted in certain cases on the basis of these conclusions.

41. When I want to modify my file, a pop-up appears asking me if I want to make a modification or an extension, what does this mean?

During 2021, only products that have been notified or modified for less than 5 years will be visible on the public site. Files older than 5 years and for which a number had been assigned will see a pop-up when you press the 'modify' button. You are given a choice between modifying the dossier if there are changes to be made, such as updating the labelling, or extending the dossier if nothing has changed since the last version. Please note that for files dating before October 2012, extension is not possible because the files are incomplete and you still have to select 'modify'. Please also note that only one name per file will be accepted.

FAQ FOOD SUPPLEMENTS and FORTIFIED FOOD

A. For which files should the notification fee be paid?

The notification fee has to be paid only when new dossiers for food supplements are submitted. It does not have to be paid for any modification of existing files or for notification files relating to fortified foods.

B. What is the processing time for a file?

The file is processed within one month. This time is the same for new files or modifications.

C. Should samples be submitted?

No. We only check administrative files. The Belgian Federal Agency for the Safety of the Food Chain is responsible for performing controls on the product market.

D. Should sweets "for sucking" be considered as "predosed forms"?

Such products should generally not be regarded as predosed forms. Sweets "for sucking" to which nutrients have been added are fortified foods that should be notified in accordance with the Belgian Nutrient Decree.

E. Which bodies are competent for monitoring food supplements?

The FPS of Health is competent for checking pre-market notification files and modifications. The Federal Agency for the Safety of the Food Chain is competent for monitoring products placed on the market for both direct and online sales. The Federal Agency for Medicines and Health Products has been delegated the task to ensure inspection and control activities in pharmacies.

F. Who is liable for selling non-compliant products?

The manufacturer, the distributor, the wholesaler or the seller can be held accountable, depending on the situation that will be assessed on a case-by-case basis. In most cases, the (Belgian) manufacturer or importer is held accountable and can possibly be fined. Shopkeepers can also be caught in breach of the law in case of direct import or distribution, if the distributor cannot be identified (if there is no invoice e.g.) or if the shopkeeper him/herself is in breach (e.g. selling non authorized product or poor standards of hygiene).

G. Regarding plant (preparation) products, which (active or toxic) substances or markers should be mentioned in the notification file?

Manufacturers and distributors are supposed to be able to determine themselves which substances should be mentioned. Relevant information can be obtained in the literature or from specialists. Both the identification and the quantity of relevant components must be stated. In the case of plants for which maximum levels of active substances and markers are determined in Column 4 of the list in Annex 3 to the Plant Decree, the levels of those substances must be expressed in terms of daily doses in the file. If the extracts used are not standardized, the minimum and maximum levels of active substances/markers can be indicated in the notification file. The maximum value must be mentioned in the field "Quantity active substance" in the Plant tab (see Section 6.2.6 of the User Manual). Additional information should be indicated in the Comment box.

We can ask for additional information if we think the data submitted are not sufficient.

H. Is my raw material permitted?

It is your responsibility to check that your product and its ingredients are safe and conform to the food legislation (Always check the last version of the legislation), in matter of identity, purity, manufacturing process where necessary and used doses. We do not validate technical files of ingredients.

I. Should Bach flower essences or floral elixirs be notified?

Products called Bach flower essences can fall under different laws. If you wish to know under which law your product should be classified, please see the guideline of the Mixed Commission relating to the classification of Bach flower essences (www.fagg-afmps.be > human medicines > grey area) (only in French or Dutch).

Products for internal use which do not fall under the medicines legislation must comply with the food legislation and particularly the Belgian Royal Decree of 29 August 1997 on the production and marketing of foods composed of plants or containing plant preparations (*arrêté royal du 29 août 1997 relatif à la fabrication et au commerce de denrées alimentaires composées ou contenant des plantes ou préparations de plantes*).

J. In which languages should plant names be indicated in the product labelling?

For all plants, the full scientific name must be mentioned (i.e. Latin name), as well as the name, if any, in the language(s) of the region where the product will be sold.

K. May predosed forms be marketed with the same formulation but with different names (brand names)?

No. Not anymore.

L. Should plant parts also be mentioned?

The indication of plant parts in the labelling is not required but can be useful. Plant parts must however be mentioned in the notification file as they can be a cause of toxicity or activity.

M. May predosed, non-prepacked products be supplied by wholesalers to retailers or packers?

Predosed products supplied to the final consumer must be prepacked. Manufacturers or wholesalers are allowed to supply products in bulk insofar as the notification file shows that those same products will not be supplied in bulk to the consumer. The notification file must include the labelling of the product as placed on the market.

N. My file has been sent to the Mixed Commission, what does that mean?

A file is sent to the Mixed Commission (Commission mixte/Gemengde commissie) – human chamber on the initiative of the Service or an operator if there is any doubt regarding the status of a product. You can find more information on the website of the Federal agency for medicines and health products (FAMHP): <u>https://www.famhp.be/en/human_use/particular_products/gray_zone</u> and contact the secretariat at the following address: <u>borderline.hum@fagg-afmps.be</u>